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Contract Number: EP-W-16-017

Work Assignment Number: 3-01

Title: Support for the Lead-Based Paint Program and Other National Program Chemicals

I. Purpose and Background

The purpose of this Work Assignment is to provide technical support of the implementation of the Renovation, Repair and Painting Program (RRP) as well as all other aspects of the Lead-Based Paint Program and of other priority existing chemicals. This is a continuation of work to extend the performance period that began under the previous work assignment, Work Assignment 2-02 of contract EP-W-16-017. No work shall be duplicated.

Title IV of the Residential Lead-Based Paint Poisoning Prevention Act requires EPA to undertake various actions to reduce the incidence of lead poisoning. These actions include technical studies to support rule making, outreach to the regulated community, outreach to the public and support of the regulatory functions.

Title IV of the Residential Lead-Based Paint Poisoning Prevention Act requires EPA to undertake various actions to reduce the incidence of lead poisoning. Specifically Section 405 (a) says "The Administrator, in cooperation with other appropriate Federal departments and agencies, shall conduct a comprehensive program to promote safe, effective, and affordable monitoring, detection and abatement of lead-based paint and other lead exposure hazards" Section 405 (d) says "the Administrator in conjunction with the Secretary of Health and Human Services...and in conjunction with the Secretary of Housing and Urban development, shall sponsor public education and outreach activities to increase public awareness..."

Throughout the year, EPA provides lead awareness and educational outreach to various audiences. In addition, EPA partners with the Centers for Disease Control and Prevention (CDC) and the Department of Housing and Urban Development (HUD) to collaborate on a theme and develop posters and flyers and other education and awareness tools and events specifically designed to observe National Lead Poisoning Prevention Week (NLPPW). EPA also promotes the Lead Week of Action, a lead awareness effort on an international scale.

Additionally, technical support is needed for other work in the National Program Chemicals Division (NPCD). NPCD is responsible existing chemicals that are ready for hazard management. Currently those chemicals include lead, mercury, formaldehyde, and asbestos. NPCD also has new responsibilities related to manufacturer requests for risk evaluations and for several existing chemicals identified as "high priority" for risk evaluation.

II. Scope of Work

Task 1 - Storage of Records

The Contractor shall arrange for storage facilities for RRP paper records. These are active records and must be available in the Washington, D.C. metropolitan area. The records must be stored in a secure area and be available for EPA personnel within 24 hours. When directed by the Contracting Officer Representative (COR), the Contractor shall arrange for pickup of additional records from within another location in the Washington, D.C. area. The Contractor shall maintain the existing filing methodology and file any new records accordingly.

Task 2 - Cleaning Verification Cards

When directed by the COR, the Contractor shall provide Cleaning Verification Cards that meet the quality control standards previously developed. The cards shall be shipped to the National Lead Information Center in Rochester, NY. It is anticipated that the cards will be produced in batches of 150,000. Assume one batch will be required.

Task 3 - Support of the Outreach Efforts at Conferences and Trade Shows

When directed by the EPA Contracting Officer Representative (COR), the Contractor shall purchase meeting rooms and exhibit space at conferences and trade shows, ship and staff the EPA-provided booth, if needed. These services include shipping the EPA booth to venues and returning it to a location designated by the COR. Also included in this task is paying for incidental fees such as conference venue drapes, delivery charges, etc.

Task 4 - Technical Studies

When directed by the COR, the Contractor shall produce studies on Lead-Based Paint issues. These studies are anticipated to be of short duration, typically less than 30 days. The exact nature of the study and due date will be contained in the technical direction. Anticipated topics are work practices on Public and Commercial Buildings and other rules in development or under consideration, including analyses on the Lead Dust Study and clearance levels.

Task 5 - Revisions to Documents

When directed by the COR, the Contractor shall provide technical support for general lead, mercury and PCBs, and other national program chemicals outreach, including revising and finalizing EPA pamphlets, poster, banners, flyers for web posting or printing, and developing outreach presentations. The Contractor shall produce both and English and Spanish versions of the documents, when directed by the COR.

Task 6 - Lead Outreach Support

When directed by the COR, the Contractor shall provide support for outreach effort to the regulated community on the Renovation, Repair and Painting Rule and/or other regulations or topics related to lead. The Contractor shall help to identify target audiences. This includes finalizing EPA pamphlets, poster, banners, flyers for web posting or printing, developing outreach presentations, translation of existing EPA documents into additional languages, and outreach support to Native American tribes (and other vulnerable communities), , the purchase of mailing lists, USB drives and CDs, , minimal printing and binding of materials (hard copy and

onto USB drives and/or CDs) (within the allowable limits of the contract) to disseminate the materials.

The Contractor shall develop posters, flyers, a resource package, web banners and other education and awareness tools specifically designed to observe National Lead Poisoning Prevention Week (NLPPW) and International Lead Poisoning Prevention Week (ILPPW).

The Contractor shall provide support for activities that encourage non-certified RRP firms to become certified or to renew their RRP firm certification in up to 4 select cities as identified by the EPA COR. Using housing inventory from the U.S. Census 5-year American Community Survey (ACS) 2017 inventory of pre-1979 housing, coupled with metrics on the number of children under 6 years old from the Census data tracking within the geographical areas, and if available, refugee population, determine which cities should be targeted to participate in the project. The activities shall include, but not be limited to, reserving venues to arrange for informational events on RRP for renovators, coordinating with building code officials, hardware stores and national trade associations to encourage those seeking renovation permits to become informed about the RRP rule, developing graphic designs for posters and web banners, radio and TV ads to announce meetings or events on RRP. The Contractor shall work with the EPA COR to determine when and what type of outreach event will be held in each specific city.

Task 7 - National Program Chemicals Support

When directed by the COR, the Contractor shall provide support to other national program chemicals including but not limited to mercury, formaldehyde, and asbestos. The Contractor shall provide technical support for regulatory and non-regulatory activities involving risk reduction and hazard management of national program chemicals. Technical support includes but is not limited to technical studies and investigation supporting risk evaluation and rulemaking, outreach to the regulated community, outreach to the public and support of regulatory and non-regulatory functions. The Contractor shall provide technical support related to manufacturer requests for risk evaluations and for several existing chemicals identified as "high priority" for risk evaluation under TSCA as directed by the EPA COR. This support will involve supporting development of risk evaluation scope documents including researching regulatory histories, identifying conditions of use, interfacing with manufacturers, users and other stakeholders, and developing supporting documents.

III. Deliverables

Tasks 1 to 3. A letter report providing statistics on the activity for the contract period shall be provided. This can be part of the monthly report.

Task 4. A draft and final report as detailed in the technical direction.

Task 5. Electronic (and/or CDs) of the professional print files of the documents ready for printing and/or posting (508-compliant) onto the EPA webpage.

Task 6. A letter report detailing the activities performed. Electronic (and/or USB or CDs) of the professional print files of any documents prepared for printing and/or posting (508-compliant) onto the EPA webpage and distribution.

For the RRP Outreach Program portion of the task, the Contractor shall provide a summary letter report of providing statistics each activity. The letter shall summarize the work completed and shall include what outreach activities occurred and the number of people reached. In addition, the report will include:

- o A description of ads printed for each outreach session in each of the cities.
- A description of the actual outreach event held in each of the cities, including the name, location of the venue, date, and time.
- A description of the number of firms contacted and sources used to develop list of renovation firms to contact.
- o An analysis of which outreach messages and delivery mechanism were most and least effective.

Task 7. A draft and final report as detailed in the technical direction.

A work plan is not required. A financial plan is required.

A QA/QC plan is required for Tasks 4 and 7. A QA/QC plan is not required for Tasks 1, 2, 3, 5 and 6.

CBI does not apply.

This work assignment relates to Tasks II, III and IV of the current Statement of Work (SOW) of the contract.

IV. Period of Performance:

This work assignment will start on June 13, 2019 and extend through June 12, 2020.

V. Level of Effort

The approximate LOE is 550 professional hours.

VI. EPA Contacts:

Work Assignment Contracting Officer Representative:

Darlene Leonard

US EPA National Program Chemicals Division

Program Assessment and Outreach Branch (7404T)

1200 Pennsylvania Avenue, NW

Washington, DC 20460

Ph: 202-566-0516

Deputy Contracting Officer Representative:

Julie Shannon

US EPA National Program Chemicals Division

Program Assessment and Outreach Branch (7404T)

1200 Pennsylvania Avenue, NW

Washington, DC 20460

Ph: 202-564-8834

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Statement of Work

Contract Number: EP-W-16-017

Work Assignment: 3-03 Amendment Number:

Title: Technical Support for the PCB Program

Background

This project is a follow-on to WA 3-03. This WA 3-03 will address 7 on-going tasks in support of the PCB program and will be funded incrementally as funding becomes available.

Scope of Work

This WA will cover the following 7 PCB tasks, with those tasks marked as being initially funded in FY19:

Task 1 will involve task management, including work plan development. **This task will be funded in FY19.**

Task 2 will involve sample collection and analysis during on-site PCB disposal or decontamination demonstrations.

Task 3 will involve PCB disposal and decontamination demonstration requiring review of sampling protocols, including stack emissions.

Task 4 will involve providing sampling kits and performance evaluation (PE) samples for PCB demonstrations.

Task 5 will involve compiling the annual PCB reports into spreadsheets and graphs. **This task** will be funded in FY19.

Task 6 will involve PCB notifications and approvals database entry into RCRAInfo.

Task 7 will involve assisting the agency with making potential regulatory changes to the PCB regulations. **This task will be funded in FY19.**

Tasks

Task 1. Task Management

The Contractor shall prepare and submit a work plan. Work under this task shall include participating in project update meetings/teleconferences, preparing the monthly progress reports and other task management.

When Tasks 2 and 4 are funded, this WA will require a Quality Assurance Project Plan (QAPP) and will require the use of TSCA CBI.

Quality Assurance Project Plans (QAPP) are required under the Agency's Quality Assurance Policy CIO-2105, formerly EPA Order 5360.1A2 and implementing guidance CIO-2105-P-01-

0. In addition to abiding by its own Quality Management Plan that has been approved by EPA, all tasks that involve the generation, collection, analysis and use of environmental data must have an approved QAPP prior to the commencement of the work.

All major deliverables (e.g., Technical Support Documents, Study Reports, Study Plans, etc.) must include a discussion of the QA/QC activities that were or shall be performed to support the deliverable. For example, a Technical Support Document or Study Report must include a clear discussion of the quality management strategies that were employed to control and document the quality of data generated and used.

The QAPP does not have to be submitted at the same time as the Technical and Financial Work Plan unless the environmental data activities covered under the QAPP must begin immediately. In many cases, planning for how to perform the work is needed before the QAPP can be prepared and submitted to EPA for approval. For example, under Task 2, when funded, the QAPP will be submitted when appropriate; however, no work involving the generation, collection, analysis and use of environmental data can begin until an EPA approved QAPP is in place.

NOTE: The tasks below represent all the possible items that may be required by EPA to support the PCB cleanup and disposal program. Written technical direction will be provided by the COR which will specify the items and quantities needed for each task.

Task 2. Sample Collection and Analysis

- A. EPA will observe on-site the PCB Disposal or Decontamination Demonstrations and will collect samples and transfer the samples to the Contractor. The Contractor shall analyze the samples appropriately, as outlined below.
 - (1) For analysis of polychlorinated biphenyls (PCBs), the Contractor shall analyze samples for classes of PCB compounds called Aroclor. These compounds include but are not limited to the following:

Aroclor 1242 Aroclor 1260 Aroclor 1016 Aroclor 1254 Aroclor 1264

- (2) For analysis of PCBs, the Contractor shall provide analytical instrument capability and methodologies to analyze and to identify the 209 congeners of polychlorinated biphenyls.
- (3) For analysis of PCBs, the Contractor shall provide analytical instrument capability and methodologies to analyze and to identify PCBs, separating and quantitating the identified PCBs in homologs from mono- to deca-chlorinated biphenyls. The analytical standard to be used shall be the Dry Color Manufacturer Association (DCMA) standard or equivalent.
- (4) The Contractor shall transmit analytical results of the demonstration samples to EPA in three stages. First, the raw data will be submitted by telephone or email as directed by the COR. These results will assist EPA in determining the efficacy of the new disposal or decontamination technologies. Second, the Contractor shall prepare a draft digital report. Third, after receiving

- comments from the COR, the Contractor shall then prepare the final analytical results which incorporate the COR's comments.
- (5) The Contractor shall analyze for other pollutants of interest as directed by the COR. For example, PCBs in the U.S. is in short supply. The possibility exists that surrogates for PCBs may necessarily be used during PCB Disposal or Decontamination Demonstration. Should surrogates be used, the Contractor shall analyze samples for the surrogates. An example of a surrogate is trichlorobenzene.
- B. Sample Media. The Contractor shall implement analytical methods suitable to the medium of interest. Examples of media include crankcase oil; mineral oil; solvents such as ethylene glycol; soils such as clay, sediment or sand; fly ash; and clinkers.

C. Sampling Kit.

- (1) The Contractor shall provide sampling kits (as described in **Task 4**) for each demonstration suitable for the collection of samples of various media, but not limited to bulk solids such as soil; and bulk liquids such as fuel oil, solvents and water.
- (2) The Contractor shall provide a sampling kit suitable for the collection and analysis of samples from porous surfaces (concrete, paint) and non-porous surfaces (metal).
- D. For thermal technologies including incineration, the Contractor may be requested by the COR to observe the collection of samples from various process streams and obtain split samples for analysis by the Contractor.
- E. The Contractor may be requested to provide personnel with appropriate experience and appropriate certificates to take the samples for any of the technologies and any of the media.
- F. The Contractor shall submit a preliminary analysis to the COR for review and comment. Upon receipt of the comments the Contractor shall incorporate the comments into the final report.

Task 3. PCB Disposal and Decontamination Demonstration Requiring Review of Sampling Protocols

- A. For thermal technologies including incineration, the Contractor may be requested by the COR to review the applicant's demonstration trial burn plan, to determine/plan the work schedule. Contractor should already be familiar with the process and equipment, from previous work with identical incinerator equipment.
- B. For thermal technologies including incineration, the Contractor may be requested to determine if the applicants' stack emission sampling protocols to be used during the trial burn comply with EPA standards.

Task 4. Sampling Kit and Performance Evaluation (PE) Samples

The Contractor shall provide, at the direction of the COR, a sampling kit for EPA PCB Disposal or Decontamination technology evaluators. Sampling items are to be shipped in a cooler ranging in size from one (1) gallon to ten (10) gallons, as appropriate. Packing material must be provided and used as appropriate to minimize breakage of items.

At minimum, the following items shall be provided in the shipping cooler:

- A. Traceability Log Forms (3 sheets minimum)
- B. Quadruplicated bar codes in self-adhering format (3 sheets 15 codes minimum per sheet). Traceability forms must accommodate bar codes and sample description.
- C. Labels for sample containers to identify samples.
- D. Disposable gloves (12 pairs minimum)
- E. Wide mouth 100 ml. sampling jars, or 40 ml. vials "VOC" sampling type, or a mixture of jars and vials as specified by COR.
- F. Spatulas, two medium size, metal
- G. One fine tip marker, waterproof
- H. Two writing pens, ball point or fine felt tip
- I. "Blue ice" or chemical ice pack for sample preservation
- J. Evidence tape, 2 feet in length
- K. Shipping bill or air bill prepared for shipping samples to Contractor on overnight basis
- L. "Zip locking" plastic bag to protect documents
- M. Extra sampling containers in case of breakage or process anomaly
- N. Paper towels, e.g. "Kimwipes"

Optional items below, which are required at times, specified by the COR, for specific projects:

- O. One-liter jars for aqueous samples, quantity to be specified.
- P. Wipe Sampling Kit:
 - (1) Folded cotton gauze pad (e.g. 4"x4"), inserted in 100 ml wide mouth jar
 - (2) Gauze pad saturated with solvent (e.g. hexane)
 - (3) Template for wiping 100 centimeter square area or as specified
 - (4) Template disposal or reusable, as specified
 - (5) Quantity to be specified by COR
 - (6) Solvent to be specified by COR
- Q. Spoon or other instruments for sampling

Blind PE samples shall be prepared to evaluate laboratory(s) designated by applicants to analyze samples for the demonstration or for commercial operations. The PE sample(s) may be prepared using various media such as sand, oil (e.g., mineral oil dielectric fluid, MODEF), or water and at various concentrations as directed by the COR (e.g., Aroclor 1260 in MODEF, 10 g in flame sealed ampules; one between 15,000 – 18,000 ppm, one between 5 -10 ppm, and one between 0.5 - 2 ppm).

Task 5. Compiling Annual PCB Reports

At the direction of the COR, the Contractor shall:

- 1) Go through 2018 annual reports (paper or electronic) that are provided by the COR and enter the facilities' data into the Excel spreadsheet file provided by the COR. The data to be entered will include the data described in the background section above.
- 2) In a document titled "PCB Annual Report Data Issues," provide to the COR a list of any missing data from any facilities, any facilities' whose annual reports the contractor was not able to decipher, and any facilities that reported data in previous years, but did not submit reports for subsequent years.

- 3) Update any graphs that are in the Excel file that the COR provides with the new data entered.
- 4) If requested by the COR, follow up with EPA Regional PCB staff or facilities to track down missing, incorrect, or illegible annual reports and make the additions or corrections to the excel spreadsheet and graphs.

Task 6. PCB Database Entry

Several Regions have either an Access database or Excel spreadsheet containing their PCB notifications and PCB approvals data. Since EPA is moving to a national PCB database in RCRAInfo, there is a need to re-enter all the data from the Regional databases/spreadsheets into RCRAInfo. In particular, Region 1's database contains 757 entries and about 20 fields that are common to both databases. This task will have the Contractor perform the data entry from the Regional databases/spreadsheets into RCRAInfo, beginning with the Region 1 database.

The Contractor shall enter as much of the PCB data from the Regional databases/spreadsheets into RCRAInfo, within the existing funding limits. Contractor will continue entering data from the Region 1 database as well as other Regional database/spreadsheets as they become available. Contractor will enter the data manually (i.e., typing) and perform a data entry quality assurance check (i.e., every field entered for every site will be double checked for correctness by a separate individual).

Task 7. Potential Regulatory Changes

The Contractor shall provide assistance to update the PCB Regulations to allow for additional extraction and analytical methods and provide other amendments which clarify the regulations. SW-846 methods for PCB extraction which are not allowed for under the 40 CFR Part 761 regulations, such as EPA Method 3541 (or Automated Soxhlet Extraction), should be compared to the existing method in the PCB Regulations – EPA Method 3540C (or Manual Soxhlet Extraction), to demonstrate equivalent or better extraction efficiencies from the newer method.

Data collection and analysis may be needed to justify a potential regulatory change for the allowance of alternate extraction methods. Only when directed, the Contractor shall assist EPA with:

- Compiling reports (e.g., analytical data report, QA/QC summary report, comparison study report);
- Maintaining records and materials generated during the data collection and analysis;
- Reviewing and responding to documents (e.g. ICR, response to comments, OMB review), and
- Collecting materials (e.g., references, the analytical data and QA/QC summary report, the comparison study report, the statistical analysis report, written articles or publications) that support the regulatory change.

This work assignment relates to Tasks I, V, and VII of the current contract statement of work.

Deliverables

Deliverable	Schedule
Task 1: Task Management	Within 30 days of issuance of Work Assignment Amendment, the Contractor shall submit a Work Plan for
Task 2: Sample Collection and Analysis	review and acceptance. Within 2 weeks of receipt of samples, Contractor will provide draft results. Within 3 weeks of the receipt of the samples the Contractor shall provide a draft report of the chemical analysis. After the COR provides comments on the draft report the Contractor shall produce a final report within 30 days of the receipt of the COR's comments.
Task 3: PCB Disposal and Decontamination Demonstration Requiring Review of Sampling Protocols	Within 20 days of receipt of a copy of the permit applicant demonstration plan, the Contractor will review and submit a summary report of the demonstration plan.
Task 4: Sampling Kit and Performance Evaluation (PE) Samples	Within 3 days of request by the COR, the Contractor will ship a sampling kit and /or performance evaluation samples to the demonstration site for use by EPA or its representative.
Task 5: Compiling Annual PCB Reports	The COR will send the necessary reports (~85-100) to the Contractor on or around July 30 th , and the Contractor shall update and finalize the excel file by August 30 th , if possible. A one- or two-week extension may be granted to the Contractor by the COR if the Contractor cannot meet this deadline.
Task 6: PCB Database Entry	Upon receipt of databases from the Regions, the Contractor shall enter the data into RCRAInfo within 10 days.
Task 7: Potential Regulatory Changes	Within 2 weeks after receiving a draft document pertaining to the potential regulatory change, the Contractor shall review and submit edits and comments. Other tasks will be performed as directed by EPA COR.

Period of Performance

This work assignment will start on the date of the contracting officer's signature and extend through June 13, 2020.

Level of Effort

The approximate LOE for this requirement is **450 hours.**

EPA Contacts

Contracting Officer Representative

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Courier Service Address:

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Alternate Contracting Officer Representative

Josh Smeraldi 1200 Pennsylvania Ave NW Mail Code 5303P Washington, DC 20460 Phone: (703) 308-0441

Courier Service Address:

One Potomac Yard 2777 S. Crystal Drive Room S-6341 Arlington, VA 22202

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Contract Number: EP-W-16-017

Work Assignment Number: 3-04

Title: Support for Formaldehyde Compliance Guides and Other Outreach

I. Purpose and Background

To provide EPA ongoing technical support to develop guidance materials for the Formaldehyde Emission Standards for Composite Wood Products regulations. This project is a continuation of work assignment (WA) 0-04 under contract EP-W-16-017. This WA continues the work initiated in WA 0-04 under contract EP-W-16-017. No work shall be duplicated. Note this change is a decrease in level of effort (LOE) hours only.

Title VI of the Toxic Substances Control Act (TSCA Title VI) establishes formaldehyde emissions for composite wood products and requires EPA to promulgate regulations to ensure compliance with these emission standards. EPA has promulgated regulations for TSCA Title VI which have requirements for manufacturers (including importers), fabricators and laminators of composite wood products. Other entities, such as retailers, wholesalers, and distributors are required to sell, supply, or offer for sale, only composite wood products that are compliant with the regulations. The regulations also establish a third-party certification program for composite wood products. The contactor shall translate and revise, as needed, small entity compliance guides, as required by the Small Business Regulatory Enforcement Fairness Act of 1996 (SBREFA) and other rule compliance-related materials as directed by the contracting officer representative (COR). The contactor shall provide, as directed by the COR, technical and graphical support for final rule implementation outreach including materials for the EPA Formaldehyde Resource Directory (website).

II. Scope of Work:

For all tasks, the contractor shall:

Task 1: Develop a Work Plan

The contractor shall prepare and submit a technical and financial work plan in accordance with the contract requirements.

Task 2: Develop Language Translations for Small Entity Compliance Guides

For each of the final English language Compliance Guides including: 1) third-party certifiers and accreditation bodies, 2) panel producers, 3) importers, distributors and retailers, and 4) fabricators (including laminators), provide up to 5 language translations, as needed and as directed by the COR. The final Compliance Guides must be in compliance with section 508 of the Rehabilitation Act.

Task 3: Provide Technical Support for EPA Formaldehyde Resource Directory (website)

The contractor shall provide support, as directed by the COR, for technical and graphical materials related to the Formaldehyde Emission Standards from Composite Wood Products final rule implementation and compliance including materials for the EPA Formaldehyde website.

III. Deliverables:

For all deliverables, the contractor shall:

Task 1: Submit a work plan within 30 working days of receipt of work assignment.

Task 2: Provide the COR revised written translations, in a language directed by the COR, of the four English language Compliance Guides within 30 working days after being tasked by the COR. The files shall be professional print-ready files and suitable for EPA web publication. The final translated Compliance Guides must be in compliance with section 508 of the Rehabilitation Act.

Task 3: As directed by the COR provide graphics, displays, forms, etc., for print or for the EPA Formaldehyde website.

A work plan is required.

A QA/QC plan is not required since no data collection applies.

CBI does not apply.

This work assignment relates to Tasks III, and IV of the current Statement of Work (SOW) of the contract. The work assignment shall start upon the Contracting Officer's signature and extend to June 12, 2020.

The Approximate Level of Effort: 90 hours

Contracting Officer Representative:

Todd Coleman
Coleman.todd@epa.gov
202-564-1208

Deputy Contracting Officer Representative:

Robert Courtnage courtnage robert a epa.gov 202-566-1081

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WORK ASSIGNMENT Statement of Work

Title: Chemical Hazard and Exposure Evaluation and Risk Management

Contractor: Battelle Memorial Institute

Contract Number: EP-W-16-017

Work Assignment (WA) Number: 3-06

Estimated Period of Performance: 06/13/19 - 06/12/20

Approximate Level of Effort: 1,220 hours

WA COR: Jeffrey Taylor

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Alternate WA COR: Tyler Lloyd

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Email: lloyd.tyler@epa.gov

Contract Level COR (CL COR): Tyrone Thomas

OPPT

Phone: 202-564-3121

Email: thomas.tyrone@epa.gov

Background:

This work assignment, entitled Chemical Hazard and Exposure Evaluation and Risk Management, was developed to provide EPA with support in analyzing primarily existing chemicals and pursuing work for those chemicals that have the highest risk.

EPA's Existing Chemicals Program addresses pollution prevention, risk assessment, hazard and exposure assessment and characterization, and risk management for chemical substances in commercial use. For the chemicals that EPA identifies as high risk, EPA will choose from among many actions that it is authorized to take under the current Toxic Substances Control Act (TSCA), as amended by the Frank R. Lautenberg Chemical Safety for the 21st Century Act. The Agency may pursue such regulatory actions as: restricting chemical use through banning its manufacture/import, issuing Significant New Use Rules that require manufacturers/importers to

alert EPA of any new uses, and publishing test rules that require the chemical industry to supply EPA with additional data. Among other options, the Agency will also analyze safer substitute chemicals and consider voluntary phase-outs from the chemical manufacturers.

Purpose and Objectives:

This work assignment continues and expands upon the work initiated under Work Assignment 2-06 of Contract EP-W-16-017. No work performed under previous work assignments will be duplicated under this work assignment.

Tasks and Deliverables:

The WA COR will review all deliverables in draft form and provide revisions or comments to the contractor. The contractor shall prepare the final deliverables incorporating the WA COR's comments. Final deliverables shall be in Microsoft Word or other appropriate electronic format requested.

Contractor personnel shall at all times identify themselves as Contractor employees and shall not present themselves as EPA employees. Furthermore, they shall not represent the views of the U.S. Government, EPA, or its employees. In addition, the Contractor shall not engage in inherently governmental activities, including but not limited to actual determination of EPA policy and preparation of documents on EPA letterhead.

The Contractor shall not duplicate any previously performed work. Also, the Contractor shall not proceed with any work that requires an approved Information Collection Request (ICR) from the Office of Management and Budget (OMB) until such approval is granted. In addition, the Contractor shall remain in compliance with OMB's Paperwork Reduction Act during the performance of this work assignment.

Task 1. Work Plan and Task Management

The contractor shall prepare a Work Plan within 15 calendar days of receipt of a work assignment signed by the Contracting Officer (CO). The Work Plan shall outline, describe and include the technical approach, resources, timeline and due dates for deliverables, and a detailed cost estimate by task and a staffing plan.

The WA COR, CL COR and the CO will review the Work Plan. However, only the CO can approve/disapprove, suggest revisions, or change the Work Plan. Official revisions will be given to the contractor by the CO. The contractor shall prepare a revised Work Plan incorporating the CO's comments, if required.

Deliverables and schedule under Task 1

1a. Work Plan within 15 calendar days of receipt of work assignment.

1b. Revised Work Plan within **3** days of receipt of comments from the WA-COR, if required.

Task 2. Quality Assurance Project Plan (QAPP)

The contractor shall submit a QAPP in accordance with the Agency requirements for QAPP (QA/R-5). Detailed information may be found at www.epa.gov/quality. The contractor shall update the QAPP as needed (and in any case, at least once a year). For QAPP revisions, the contractor shall provide a list summarizing the changes from the prior approved QAPP. The QAPP should document the planning, implementation, and assessment procedures for subtasks 3, 5, 6, 7, and 8 in this SOW, as well as any specific quality assurance and quality control activities. The QAPP integrates all of the technical and quality aspects of the project in order to provide a blueprint for obtaining the type and quality of environmental data and information needed for a specific decision or use.

Task 3. Rulemaking Support

The contractor shall help EPA develop rules, such as TSCA section 4 test rules that secure additional chemical data, section 5 Significant New Use Rules (SNURs) that affect new uses, and section 6 rules that restrict chemicals. Work may include analyzing literature sources or managing information that was developed by EPA or outside entities (e.g., other agencies, states, countries, NGOs, foundations, universities, and companies). The contractor may help collect, organize, and summarize public comments that are submitted by entities such as public interest groups, industry, academia, and others to EPA rulemaking dockets.

Task 4. Meeting & Workshop Support

The contractor shall assist EPA with meeting support by taking notes during meetings, such as at 1-to-2-hour meetings that involve a specific chemical or category of chemicals of concern, or at rulemaking consultation meetings that deal with tribal, small business, and state issues. The contractor will produce the meeting notes and also incorporate any edits to those notes provided by EPA. The contractor will support expert meeting workshops, such as regarding labeling for paint removal chemicals, and these workshops could require the contractor do many services, such as solicit attendees, organize logistics, facilitate the workshop, and summarize the discussions that take place at the workshop.

Task 5. Chemical Prioritization & Work Plan Chemicals

The contractor shall assist EPA with identifying priority chemicals for risk management analysis. Work could include securing lists of chemicals that are being analyzed by: other countries, states within the United States, and EPA or other Federal agencies. The contractor may present information related to hazard, exposure, risk, and different environmental mediums such as air,

water, and soil. The contractor may help EPA identify and take follow-up action on Work Plan chemicals that generally have the greatest risk concerns.

Task 6. Chemical Data Reporting (CDR)

The contractor shall assist EPA with managing chemical data under its CDR. Support can include preparing for the 2020 CDR, working with existing 2016 CDR and 2012 CDR data, helping with Internet and outreach materials, and producing statistics and chemical lists that relate to production volume, companies, industrial processing and use, and consumer and commercial use, among other information.

Task 7. High Production Volume (HPV) Chemical Management

The contractor shall continue to maintain HPV Challenge Program records, and conduct queries on HPV Challenge Program data if needed. The contractor may also perform work with other HPV chemicals.

Task 8. Miscellaneous Hazard, Exposure, and Risk Analyses

The contractor shall conduct analyses regarding other miscellaneous hazard, exposure, and risk management projects as the need arises.

Summary of Deliverables:

Task 1	The contractor shall prepare and submit the work pla requirements.	The contractor shall prepare and submit the work plan in accordance with contract requirements.							
Task 2	Quality Assurance Project Plan (QAPP) • Initial QAPP • Revised QAPP(s)	 10 days after WA begins Prior to work on environmental data activities 							
Task 3	Rulemaking Support	At WA COR's Request.							
Task 4	Meeting & Workshop Support	At WA COR's Request.							
Task 5	Chemical Prioritization & Work Plan Chemicals	At WA COR's Request.							
Task 6	Chemical Data Reporting (CDR)	At WA COR's Request.							
Task 7	HPV Chemical Management	At WA COR's Request.							
Task 8	Miscellaneous Hazard, Exposure, & Risk Analyses	At WA COR's Request.							

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		Work As	ssignment			Other	Amendm	ent Number:
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Contract Number: EP-W-16-017

Work Assignment Number: 3-10

<u>Title</u>: New Chemical Program Support

Purpose:

This work shall be performed under Battelle Contract EP-W-16-017, Task III Technical Program Support-General Support. This work assignment provides support to the New Chemical Program (NCP) in processing of Pre- Manufacturer Notices (PMNs). No work performed under previous work assignments will be duplicated under this work assignment.

I. Background:

This work assignment, entitled New Chemicals Program Support, is to provide EPA with support to expedite the processing of the Pre-Manufacturer Notices (PMNs) to reduce the backlog and provide support brought about by the enactment of the Frank R. Lautenberg Chemical Safety for the 21st Century Act. This law became effective immediately upon being signed on June 22, 2016. The activities listed below will be an ongoing effort to: Provide PMN Status Tracking, Draft Letters and Consent Orders, Draft documentation needed for Significant New Use Rules (SNURs) and Statement on Administrator Finding to be published in the Federal register. Populate the Pre- Notice Communications Database, Provide Administrative Support to the New Chemicals Ad HOC Committee, and Provide Miscellaneous Administrative Support to the New Chemicals Program as the program changes to implement the new law.

EPA's New Chemicals Program is required to review and make an affirmative determination of risk on new chemical substances submitted for evaluation in premanufacture notices (PMNs) and significant new use notices (SNUNs) before manufacturing, processing and or use can commence. The review evaluates a new chemical substance given the information provided by the submitter of the PMN and the information readily available to EPA to determine if the new chemical substance poses a risk to human health or the environment. This review includes an evaluation of physical and chemical characteristics of the substance, the fate, the human health and environmental hazards, exposures, and risk management to make the affirmative determination of risk. Once the determination is made EPA may regulate the manufacturing, processing and or use of a new chemical substance through a Consent Order and/or Significant New Use Rule (SNUR) which requires manufacturers/importers to alert EPA of any new uses of the new chemical substance. If the determination of not likely to present an unreasonable risk to human health or the environment is made, a notice of the determination must also be published in the Federal Register.

II. Scope of Work:

The Contractor Shall:

Task 1. Work Plan and Monthly Progress Report - Section II.C.3, paras 1-5, page 7; Section II.J, para 1, pages 10-11

- (A) Submit a work plan describing tasks, approach, schedule, estimated direct labor hours by task and labor level, budget with costs broken down by line item; and proposed staff names, hours, and project roles.
- (B) Provide a table in the Monthly Progress Report with the information shown below:

Memo #	Date	EPA Technical	Contractor	Topic	Hours	Used this	Cum used
and date	due	Contact	lead staff		Allocated	month	

Through technical direction, the WAM will identify topics to address, estimated hours for each topic, a deliverables due date, and background such as the names of EPA staff to contact for information.

(C) Some work may require access to TSCA Confidential Business Information. The manager of this work assignment, as well as any staff working on reports that involve TSCA CBI, must be TSCA CBI cleared. They must also take supplementary CBI training designated by the EPA Contracting Officer Representative. Reports based on information drawn from TSCA CBI documents must be submitted to EPA as TSCA CBI, even if the contractor believes they have excluded CBI from the report. This is in addition to complying with all TSCA CBI requirements in the contract and in EPA's TSCA CBI Protection Manual.

Task 2. Quality Assurance Project Plan (QAPP) - Section II.C.3, paras 1-5, page 7; Section II.J, para 1, pages 10-11

The contractor shall submit a Quality Assurance Project Plan (QAPP) in accordance with the Agency requirements for QAPP (QA/R-5). Detailed information may be found at www.epa.gov/quality. The contractor shall update the QAPP as needed (and in any case, at least once a year). For QAPP revisions, the contractor shall provide a list summarizing changes from the prior approved QAPP.

Task 3. Document Sanitization- Section II.C.3, paras 1-5, page 7; Section II.J, para 1, pages 10-11 The contractor shall sanitize documents by removing Confidential Business Information (CBI) from Risk Assessment Division (RAD) Section 5 Risk Assessment documents. This will increasingly be asked for by companies as EPA eliminates the practice of sending Action Letters immediately drafting Consent Orders

to be sent to PMN submitters upon finalization of the affirmative risk finding and development of risk management options.

Task 4. Tracking Support- Section II.C.3, paras 1-5, page 7; Section II.J, para 1, pages 10-11 Complete simple spreadsheet created by NCP to track progress of eliminating the back log of cases as well as tracking the completion of information requests sent by PMs to be completed by RAD. PMs will provide the status/ milestones to be tracked and added to the spreadsheet.

Task 5. Consent Order and SNUR Development - Section II.C.3, paras 1-5, page 7; Section II.J, para 1, pages 10-11

Provide support in developing draft TSCA section 5(e) Consent Orders and SNURs.

After collecting documentation from the Program Manager (PM) to include briefing papers, draft action letters, and other correspondence as well as data and information in PMN Gold and submitted PMNs, draft Consent Orders and SNURS. Drafts will be developed from boiler plates following instructions and using the information collected. After Draft is completed review with PM and prepare printed document for review and signature.

Task 6. Miscellaneous Administrative Support- Section II.C.3, paras 1-5, page 7; Section II.J, para 1, pages 10-11

Provide miscellaneous support to the New Chemicals Program as needed, which may include preparation, scanning, shredding, uploading etc. of documents and file; database creation, population and maintenance; document control; completing information requests from management; and tracking progress of work effort to eliminate backlog of cases and information requests from Program Managers to the Risk Assessment Division.

Task 7. Determination Support - Section II.C.3, paras 1-5, page 7; Section II.J, para 1, pages 10-11 Provide support, to make available to the public, all underlying documents supporting EPA's risk determinations. This support will include sanitization of the determination and related support documents by removing Confidential Business Information (CBI); preparation of documents and language such as preambles and the statement of finding developed from boiler plates, following instructions and using the information in the determination and support documents; uploading documents into the appropriate public docket; and miscellaneous related support.

III. Deliverables:

Task 1.	The contractor shall prepare and submit the work plan in accordance with contract
	requirements.

Task 2.	Quality Assurance Project Plan (QAPP) Initial QAPP Revised QAPP(s)	10 days after WA beginsPrior to work on environmental data activities
Task 3.	Document Sanitization	At WAM's Request.
Task 4.	Consent Order and SNUR Development	At WAM's Request.
Task 5.	Miscellaneous Administrative Support	At WAM's Request.
Task 6.	Determination Support	At WAM's Request.

- A Quality Assurance Project Plan (QAPP) is necessary. The contractor shall implement a quality
 system that meets ANSI standard E4-2014 and prepare a QAPP following OPPT/EPA guidelines. No
 work on the conduct of environmental data operations can begin until EPA approval of the QAPP is
 obtained.
- · CBI does apply.
- Contractor personnel shall at all times identify themselves as contractor employees and shall
 not present themselves as EPA employees. Furthermore, they shall not represent views of the
 U.S. Government, EPA, or its employees. In addition, the contractor shall not engage in
 inherently governmental activities, including but not limited to actual determination of EPA
 policy and preparation of documents on EPA letterhead other than routine correspondences.

IV. Period of Performance:

This Work Assignment will start with the date of the Contracting Officer's signature and extend through - June 12, 2020.

V. Level of Effort:

The approximate level of effort for this work assignment is 3937 professional hours.

VI. EPA Contacts:

Contracting Officer Representative

Rebecca Cool

Christopher Buckley

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Cool.Rebecca@epa.gov

Alternate Contracting Officer Representative

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1200 Penn. Ave, NW, Washington, DC 20460

Phone: (202) 564-4817

Buckley.christopher@Epa.gov

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Contra	cting Official	Name Jody	Gosnell -		•			nch/Mail Code:		
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Statement of Work

Contract Number: EP-W-16-017 **Work Assignment Number:** 3-12

Title: Support for CBI Reviews as Required by TSCA section 14(g)

Purpose:

The Purpose of this Work Assignment is to assemble and extract selected data from TSCA submissions containing information claimed as CBI, and provide a written analysis sufficient to allow for the program office consideration of the validity of the identified CBI claims and then the generation of a recommendation to meet the requirements for a final determination as required under TSCA section 14(g) data related to submitted with new chemical notices and input the information into appropriate databases. The level of detail will vary depending on the type of filing subject to review, and relevant statutory, regulatory and policy considerations.

I. Background:

The Office of Pollution Prevention and Toxics (OPPT) is charged under the Toxic Substances Control Act (TSCA) with reviewing confidential business information (CBI) claims and making recommendations for final determinations concerning the potential validity of these claims. TSCA section 14(g). Because of the statutory mandate that these reviews occur within ninety days of receipt of the documents, identification of the claims, initial data entry, data assembly/extraction, and creation of useful and related information products must occur in a timely fashion in order for it to be used in the statutorily mandated process. These documents will be TSCA submissions directed to the Agency under all provisions of TSCA, as well as follow-up materials, including amendments and substantiations or responses to requests for comments. To address this broad need, the EPA will rely on contractor support to assist in the extraction, summary, and initial analysis/assessment of the data to facilitate the Agency CBI review and determination process.

II. Scope of Work:

Subtask 1. Work Plan and Task Management

The Contractor shall: Submit a work plan that describes tasks, the planned approach, schedule, estimated direct labor hours by labor level, and associated budget. The Contractor may request a meeting (via conference call) with the At Contracting Officer Representative (COR) to seek clarification or to answer any questions prior to the submission of the above work plan.

Upon approval of the work plan, the Contractor shall maintain at least biweekly communication with the At Contracting Officer Representative (COR) regarding the status of the work assignment. Additional points of contact under this work assignment are noted below in VI EPA contacts.

Subtask 2. Quality Assurance Project Plan (QAPP)

A Quality Assurance Project Plan (QAPP) is required. A Quality Assurance Project Plan documents the planning, implementation, and assessment procedures for a particular project, as well as any specific quality assurance and quality control activities. It integrates all the technical and quality aspects of the project in order to provide a "blueprint" for obtaining the type and quality of environmental data and information needed for a specific decision or use. All work performed or funded by EPA that involves the acquisition of environmental data must have an

approved Quality Assurance Project Plan. Details for developing a QAPP can be found at: https://www.epa.gov/sites/production/files/2015-06/documents/g5-final.pdf and the Contractor shall be responsible for the development and revisions to the QAPP.

Subtask 3. TSCA CBI reviews

The Contractor shall: Review all documents subject to the TSCA 14(g) CBI review requirements, and extract from each file the data and studies pertinent to the assessment of the CBI claims. These will largely be extracted from substantiations as authorized under the regulations and policies provided by the information submitters.

- a. The Contractor shall cause the data to be abstracted and entered into the designated database or spread sheet or template.
- b. The Contractor shall also summarize the basis for the submitters' claims of confidentiality, providing specific sources for the summary points (e.g. loss of competitive advantage, Response 3, secret that substance is in commerce, Response 6 etc.) The Contractor shall provide a written analysis sufficient to allow for the Program Office consideration of the validity of the identified CBI claims.
- c. The Contractor shall be called to engage in literature searches related to the reviews.
- d. The activities and the generated work-products of the Contractor shall be assembled into formats and template of the Program Office's design.
- e. The Contractor shall participate in meetings and trainings related to TSCA CBI reviews and incorporate EPA procedural updates in to the workflow as appropriate.

Subtask 4. Confidentiality

The majority of the material related to this activity is claimed by the submitters as TSCA Confidential Business Information, TSCA CBI clearance and adherence to TSCA CBI procedures are required through the duration of the WA.

III. Deliverables:

Subtask 1.	The contractor shall prepare and submit the work plan in accordance with contract requirements. Upon approval of the work plan, the Contractor shall maintain at least biweekly communication with the At Contracting Officer Representative (COR).	 At the start of the WA. Bi-weekly status meetings with At Contracting Officer Representative (COR).
Subtask 2.	Quality Assurance Project Plan (QAPP) Initial QAPP Revised QAPP(s)	10 days after WA beginsPrior to work on environmental data activities
Subtask 3.	TSCA CBI reviews	 To be completed within 40 days of receipt of an approved submission. Following guidance provided by Contracting Officer Representative (COR).
Subtask 4.	The Contractor shall gain and maintain TSCA CBI clearance through the duration of the work assignment	At the start of the WA.

• EPA will approve the work plan within 45 days.

A Quality Assurance Project Plan (QAPP) is required. The contractor shall implement a quality system that meets ANSI standard E4-2014 and prepare a quality assurance project plan (QAPP) following OPPT/EPA guideline. No work on the conduct of environmental data operations can begin until EPA approval of the QAPP is obtained.

- · A work plan is required.
- · CBI does apply.

IV. Period of Performance: the WA will begin on the date of the Contracting Officers Signature and end on 6/12/2019

<u>V.</u> The approximate LOE is: 3000 professional hours.

VI. EPA Contacts:

Primary Contracting Officer Representative

Skyler Dobert WJC East Building, Rm 4218-C, MC 7408M 1200 Penn. Ave, NW, Washington, DC 20460

Phone: (202) 564-3159 Dobert.skyler@epa,gov

Alternate Contracting Officer Representative
Tyrone Thomas
OCSPP/OPPT/EAD U.S. Environmental Protection Agency Washington, DC 20460 (202) 564-3121

EPA			United	l States Environm Washin		Work Assignment Number 3-14					
					ssignment	·	Other Amendment Number:				
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Project Officer Name Tyrone Thomas								Branch/Mail Code:			
							Pho	Phone Number: 202-564-3121			
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Contract Number: EP-W-16-017

Work Assignment Number: 3-14

<u>Title</u>: EPA Office of Science and Coordination Policy and Office of Pollution and Prevention and Toxics Alternative Testing Strategy, Data Science, and Systematic Review Support

Contracting Officer Representative

Kristan Markey

Office of Science Coordination and Policy Exposure Assessment Coordination and Policy

Division

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Email: markey.kristan@epa.gov

Alternate Contracting Officer Representative

Cory Strope

Office of Pollution Prevention and Toxics

Risk Assessment Division

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Email: strope.cory@epa.gov

Purpose:

This work assignment, EPA Office of Science and Coordination Policy, Alternative Testing Strategy, Data Science, and Systematic Review Support, will provide technical support to the Office of Science Coordination and Policy (OSCP) in EPAs Office of Chemical Safety & Pollution Prevention (OCSPP) including the implementation of the EPA Office of Pollution Prevention and Toxics (OPPT) Alternative Testing Strategy, performance-validation of high throughput (HT) assays, computational models for the estrogen, and thyroid pathways and cross-species validation studies; and development and prioritization of chemicals in EPA's Endocrine Disruptor Screening Program. No work performed under previous task orders or work assignments will be duplicated under Work Assignment 3-14, EP-W-16-017. However, some of the work is a continuation of EP-W-16-017 Work Assignment 2-14.

I. Level of Effort

The approximate LOE for this work assignment is 2,120 hours. This includes a request for:

- 104 hours for Task 1
- 16 hours for Task 2
- 1300 hours for Task 3
- 700 hours for Task 4.

II. Background

This work assignment will provide technical support in two specific areas:

- 1. Task 3. Support the implementation of the EPA Office of Pollution Prevention and Toxics (OPPT) Alternative Testing Strategy under Section 4 of the Frank R. Lautenberg Chemical Safety for the 21st Century Act; and
- 2. Task 4. Task 4. Support EDSP and OPPT systematic literature reviews for the development of risk evaluations and new alternative methods (NAMs) including performance-based validation of high throughput (HT) assays and computational models.

The Office of Science and Coordination Policy manages EPA's Endocrine Disruptor Screening Program (EDSP). The EDSP was established in 1998 under authorities contained in the 1996 Food Quality Protection Act (FQPA) and the 1996 Safe Drinking Water Act (SDWA) amendments. As mandated by these statutes, the EDSP develops

a screening program to determine whether certain substances may have endocrine activity in humans and wildlife. The US EPA has developed a two-tiered approach for screening chemicals and pesticides. The Tier 1 battery is used to identify substances that have potential to interact with the estrogen, androgen or thyroid hormone pathways. The Tier 2 tests identify and establish dose response information for adverse effects for substances identified in the Tier 1 screening. Beginning in 2015, the EDSP is incorporating ToxCast high throughput screening data and computational models in the prioritization and screening of a chemical's potential to interact with the endocrine system in humans and wildlife for a portion of the Tier 1 battery. This approach will allow nearly 20 times the current number of screenings to be performed while nearly eliminating animal testing, allowing the program to meet its goals with a relatively level budget.

The EPA's EDSP is continuing the development and validation of alternative testing methodologies (i.e., high throughput assays and computational tools) to prioritize and screen chemicals based on potential endocrine bioactivity and exposure--in particular, the estrogen, androgen, or thyroid hormone pathways in humans and wildlife. This increased use of alternative testing methodologies will improve the output of screening results allowing for greater coverage of the endocrine system. EDSP is also supports the incorporation of endocrine endpoints and NAMs into regulatory programs such as TSCA.

I. Statement of Work

Task 1. Work Plan and Task Management

- The contractor shall prepare and submit a work plan in accordance with the requirements of this contract.
 The work plan will describe tasks, approach, schedule, estimated direct labor hours by task and labor level, budget with costs broken down by line item; and proposed staff names, hours, and project roles.
 Work under this subtask will include participating in conference calls, preparing monthly progress reports, and other task management activities.
- 2. Provide a table in the Monthly Progress Report with the information shown below:

					Hours	Hours used	Cumulative
Memo #	Date	EPA	Contractor	Topic	Allocated	this month	hours used
and date	due	technical	lead staff				
		Contact					

Through technical direction, the COR will identify topics to address, estimated hours for each topic, a deliverables due date, and background such as the names of EPA staff to contact for information.

- 3. Some work may require access to TSCA Confidential Business Information. The manager of this work assignment, as well as any staff working on reports that involve TSCA CBI, must be TSCA CBI cleared. They must also take supplementary CBI training designated by the EPA COR. Reports based on information drawn from TSCA CBI documents must be submitted to EPA as TSCA CBI, even if the contractor believes they have excluded CBI from the report. This is in addition to complying with all TSCA CBI requirements in the contract and in EPA's TSCA CBI Protection Manual.
- 4. The contractor shall immediately notify the EPA WA COR if there are any problems that affect the production and delivery of deliverables.

- 5. The contractor shall provide all deliverables in an electronic format specified by the EPA WA COR (e.g., Word, Excel, Access, HTML) via electronic mail. Unless otherwise specified by the EPA WA COR, Battelle shall provide a secure method for internet transfer of large files.
- 6. All Deliverables for WA 3-14 are the property of EPA (including any scripts or computer code developed accomplish analyses).
- 7. The contractor shall format any deliverables intended for posting on an EPA public website to comply with Section 508.

Task 2. Quality Assurance Project Plan (QAPP)

The contractor shall create a Quality Assurance Project Plan (QAPP) that documents the planning, implementation, and assessment procedures for subtasks 3 and 4, in this SOW, as well as any specific quality assurance and quality control activities. The QAPP integrates the technical and quality aspects of the project in order to provide a blueprint for obtaining the type and quality of environmental data and information needed for a specific decision or use. All work performed or funded by EPA that involves the acquisition of environmental data must have an approved QAPP. Details for developing a QAPP can be found at: https://www.epa.gov/sites/production/files/2015-06/documents/g5-final.pdf and the contractor shall be responsible for the development of, and any revisions to, the QAPP. Revisions to the QAPP must be made prior to beginning environmental data activities.

Task 3. Support the implementation of the EPA Office of Pollution Prevention and Toxics (OPPT) Alternative Testing Strategy under Section 4 of the Frank R. Lautenberg Chemical Safety for the 21st Century Act

This Task fits specifically under the Contract SOW Task II. Data Analysis (II. 1-6).

- 1. **Data Processing on Existing Chemical Data**. The Contractor shall convert data from TSCA Sections 4, 5, 6, and 8 hazard, exposure, and fate databases not previously converted under WA 2-14 into a machine-readable format (such as ASCII). The contractor shall establish database links for the chemical, guideline, case number, and associated text as pertains to each record.
- 2. **Data Analysis.** The Contractor shall continue to analyze which tests are most commonly requested, required, and available, and determine trends of data based on chemical classes and other variables as directed by EPA. This knowledge will be used to help optimize future testing strategy (data requests) and to determine tests that would most benefit from alternative testing strategies.
 - a. The Contractor shall support the curation, clustering, and prioritization of chemical substances from the TSCA Inventory including analysis of substance nomenclature, chemical structure, and data on physical-chemical properties, use and exposures, and toxicology.
- 3. Transformation of OPPT data to OECD Harmonized Templates. The Contractor shall convert data from TSCA Sections 4, 5, 6, and 8 hazard, exposure, and fate databases into appropriate OECD Harmonized Templates based on Subtask 3.1 and shall upload this data into OPPT's IUCLID installation. As directed by EPA, the Contractor shall identify and implement approaches to extend the IUCLID system, integrate the system into other EPA systems, and develop workflows and interfaces in order to meet EPA's scientific and programmatic needs.

- 4. **Scientific Platform.** The Contractor shall install and maintain software on the TSCA CBI LAN in Linux and Windows environments in support of this project and for the TSCA NAM Team to support the overall implementation of the TSCA Alternative Testing Strategy. This includes, but is not limited to, R environments and packages, Python environments and packages, relational and non-relational databases (MySQL, PostgreSQL, MongoDB, etc.), internally-facing web applications, etc.
- 5. **Case Studies.** The Contractor shall support the development and execution of TSCA Alternative Testing Strategy case studies of mutual interest to OPPT and OSCP including analysis of chemical structure, in vivo, in vitro data, and exposure data.

Task 4. Support EDSP and OPPT systematic literature reviews for the development of risk evaluations and new alternative methods (NAMs) including performance-based validation of high throughput (HT) assays and computational models

This Task contains elements under both Task II. Data Analysis (II. 4 - 6) and Task III. Technical Program Support - General Support (III.1, 2, & 4).

- 1. **EDSP pathway-based systematic literature review pilot and analysis**. The Contractor shall assist EPA with developing and implementing approaches for a pilot on the thyroid-related networks pathway-based systematic literature review. Tasks include articles tagging, title/abstract screening, full-text screening, data extraction, and other annotations as directed by EPA on relevant articles, as well as template design, workflow management, and support of automated approaches.
- Data management of Systematic Reviews. The Contractor shall support the development and
 implementation systematic review templates (including the use of OECD Harmonized Templates,
 controlled vocabularies, etc.), reviewer workflows, and reference management in systematic review tools
 selected by EPA.
- 3. **Analysis of Systematic Reviews**. The Contractor shall support the data (including data cleaning), statistical (such as meta-analysis of studies), visualization, toxicological, and textual analysis (such as text mining and natural language processing analysis) of systematic reviews and other data streams.

II. Deliverables

The contractor shall provide deliverables as shown in Table 1.

Table 1. Deliverables and Schedule

For tasks 3 & 4, the Work Assignment COR's shall develop and provide specific technical direction to begin scoping the project. The deadlines are intended to be illustrative only for workplan development purposes.

Task	Subtask	Deliverable	Projected Due Dates		
Task 1. Work Plan and Task		The contractor shall prepare and submit the work plan in accordance with contract			
Management		requirements.			

Task	Subtask	Deliverable	Projected Due Dates	
Task 2. Quality Assurance Project Plan (QAPP)		Draft QAPP Final QAPP	Draft: 10 days after WA begins Final: Prior to work on environmental data activities	
Task 3. Support the implementation of the EPA Office of Pollution Prevention and Toxics (OPPT)	3.1	Loading of OPPT data (toxicological, environmental fate, physical-chemical, exposure) into EPA enterprise (MySQL, Postgresql) systems (no report)	At Work Assignment COR's request.	
Alternative Testing Strategy under Section 4 of the Frank R. Lautenberg Chemical Safety for the 21st Century Act	3.2	 Naïve TSCA inventory clustering exploration and analysis (report) Naïve TSCA inventory clustering exploration and analysis combined with available in vivo, in vitro, and other TSCA-relevant data (report) 	1. 7/30/2019 2. 10/30/2019	
Century Act	3.3	 Pilot of existing EPA ecological toxicity data uploaded in the OPPT IUCLID instance (abbreviated report) Development, implementation, and support of user workflows to support new extraction of ecological data directly in OPPT IUCLID instance (no report) 	1. 7/30/2019 2. 8/30/2019	
		3. Further work and direction following steps 1 & 2	3. At Work Assignment COR's request.	
	3.4	Installation and management of OPPT CBI LAN Linux and Windows Sandbox and Production Application Software	At Work Assignment COR's request.	
	3.5	 Completion and analysis of two NAM templates as a case study (abbreviated report) Analysis of literature search and data mining of relevant physical-chemical properties, in vitro, 	1. 8/15/2019 2. 8/15/2019	
		and in vivo for inhalation exposures to inform additional structural alerts (including report) 3. Analysis and data mining (including report) of the ecological toxicity as it relates to ECOSAR categories (especially neutral organics)	3. 9/15/2019	
		 (including report) 4. Inhalation exposure decision-tree model from Deliverable #2 implemented in the QSAR toolbox profiler 	4. 9/15/2019	
		5. Additional case studies at Work Assignment COR's request.	5. At Work Assignment COR's request.	

Task	Subtask	Deliverable		ed Due Dates
Task 4. Support EDSP and OPPT systematic literature reviews for the development of risk evaluations and new alternative methods (NAMs) including	4.1	 Completion of Thyroid NIS calibration analysis and update (report) Thyroid NIS pilot article review (no report, just completion) Other deliverables at Work Assignment COR's request 	1. 2. 3.	6/15/2019 9/30/2019 Other deliverables at Work Assignment COR's request
performance-based validation of high throughput (HT) assays and computational models	4.2	 Completion of Pubertal SR Forms linked to OECD Harmonized Templates and other controlled vocabularies (no report) Other deliverables at Work Assignment COR's request 	2.	7/15/2019 Other deliverables at Work Assignment COR's request.
	4.3	 Update Thyroid NIS literature search strategy and ontologies (including report) Thyroid NIS pilot article analysis and NLP model development (including report) Other deliverables at Work Assignment COR's request. 	1. 2. 3.	7/15/2019 10/30/2019 Other deliverables at Work Assignment COR's request.

- 1. EPA will approve the work plan within 30 days.
- 2. A Quality Assurance Project Plan (QAPP) is required. The contractor shall implement a quality system that meets ANSI standard E4-2014 and prepare a QAPP following OPPT/EPA guidelines. No work on the conduct of environmental data operations can begin until EPA approval of the QAPP is obtained.
- 3. This work assignment involves the use of TSCA Confidential Business Information (CBI) for Task 2; otherwise, no CBI is involved.
- 4. Contractor personnel shall at all times identify themselves as contractor employees, and shall not present themselves as EPA employees. Furthermore, they shall not represent view of the U.S. Government, EPA, or its employees. In addition, the contractor shall not engage in inherently governmental activities, including, but not limited to actual determination of EPA policy and preparation of documents on EPA letterhead other than routine correspondences.

III. Period of Performance

This Work Assignment will start with the date of the Contracting Officer's signature and extend through June 12, 2020.

United States Environmental Protect					ental Protection A	Agency	Work Assignment Number				
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Contract Number Contract Period 06/13/2016 To 06/12/2020								Title of Work Ass	ignmer	nt/SF Site Nam	 е
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PERFORMANCE WORK STATEMENT EP-W-16-017 Work Assignment 3-15

TITLE: Fish Tissue Data Migration

WORK ASSIGNMENT COR (WA-COR): Samantha Fontenelle

Standards & Health Protection Division

US EPA (4305T)

Washington DC 20460

202-566-2083 202-566-0409 FAX

Lisa Larimer (Alternate)

202-566-1017 202-566-0409 FAX

PERIOD OF PERFORMANCE: Work Assignment issuance through 06/12/2020

I. Background and Scope of Work

Background

The National Listing of Fish Advisories (NLFA) is a national online database of fish advisories and fish tissue contaminant data collected by states, territories and tribes (hereafter states). It was developed in 1992 and includes advisory information for 50 states, District of Columbia, and the U.S. territories of American Samoa and Guam. It also includes fish tissue contaminant data which served as the basis for state-issued advisories for 48 states. Since 2000, the survey of fish advisories has been performed under an approved ICR for the National Listing of Advisories (OMB Control No. 2040-0226).

Scope of Work

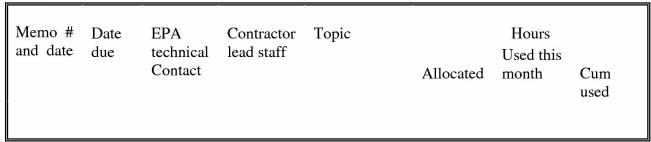
Under this work assignment, the contractor shall assist EPA with the collection, standardization, and migration of state fish tissue contaminant data to the Water Quality Exchange (WQX); and/or assist states with converting their data into the WQX XML format and importing it into WQX.

II. Tasks

Task 1 - Work Plan and Monthly Progress Report

The contractor shall submit a work plan to the Agency within fifteen (15) calendar days of receipt of the WA. The contractor work plan shall describe tasks, approach, schedule, estimated direct labor hours by task and labor level, budget with costs broken down by line item; and proposed staff names, hours, and project roles.

The contractor shall provide a table in the Monthly Progress Report with the information shown below:



Task 2 - Quality Assurance Project Plan (QAPP)

A Quality Assurance Project Plan (QAPP) has been approved by the Contractor's quality assurance/quality control (QA/QC) officer and the EPA/OST QA/QC officers under WA 1-15. This document is a living document and updates shall be made as necessary (e.g., due to changes in scope, key personnel or approach). All deliverables shall include a report describing compliance with the QAPP. The work performed in this PWS shall conform to the Information Quality Guidelines (IQG) Checklist (Attachment A). The completed checklist and final QAPP shall be submitted with the final deliverables.

Task 3 - Data Management Plan

The Data Management Plan was revised under WA 1-15. The Contractor shall update this document as necessary to ensure that the approach for collecting, standardizing, and migrating state fish tissue data is appropriately documented and reproducible.

Task 4 - Tissue Data Collection and Preparing Data for Import

Data quality issues exist with the state fish tissue contaminant data in the NLFA. For this reason as a lack of the required fields for data import into WQX, EPA anticipates that states may elect not to migrate this data to WQX.

Based on written technical direction from the WACOR, the contractor shall assist with collecting new tissue data; standardizing/converting data in flat files (Excel, etc) to WQX-compatible XML files; and addressing any other data related issues. The data review and conversion shall be done to ensure that tissue data migrated to WQX is appropriately formatted to be successfully imported.

For estimating purposes, the Contractor shall assume data from 6 states will be reviewed and converted to an WQX-compatible XML file with required data fields. The Contractor shall support EPA in timeframes specified by the WACOR. This task will require the Contractor work closely with states.

Task 5 - State Fish Tissue Data Import to WQX

The Contractor shall work closely with EPA and states to ensure their tissue data are accurate and complete before they are migrated to WQX. The contractor shall notify EPA and/or the states if there are any import errors if data files fail import and provide recommendations on how to fix errors.

Once tissue data are imported into WQX, the Contractor shall notify each state of its data being successfully imported into WQX. Tasks 4 and 5 activities shall be done in collaboration with each state.

Task 6 - EPA Fish Tissue Data in WQX

The EPA data (OST_SHPD) dataset includes fish tissue data from three studies: GLHHFTS2010, NRSA0809 and NRSA 1314. The contractor shall also support EPA with addressing issues identified with this dataset. This support may include data conversion/mapping to the WQX web XML format and import into WQX.

Task 7 – General Technical Support

The contractor shall provide general technical support which may include responding to inquiries on state tissue data or on the NLFA database; attending monthly fish workgroup calls; preparing or supporting the preparation of presentations; and training state fish program staff on preparing and importing data to WQX using WQX web template. For estimating purposes, the Contractor may assume no more than two presentations will be prepared and three 1-hr training sessions on WQX.

III. Deliverables

The Contractor shall prepare draft deliverable(s) for review by the EPA WACOR in accordance with the deliverable schedule in section IV or by technical direction (TD). In preparing final written deliverables the Contractor shall incorporate written comments from the EPA WACOR and submit the final deliverables in accordance with the deliverable schedule in section IV or TD. The EPA WACOR will review and approve all final deliverables.

Draft and final deliverables including reports, data, databases and maps shall be provided to the WACOR electronically. Electronic files shall be provided in PDF and/or in the original software (Excel, Word). The Contractor shall use Microsoft Office and Adobe Acrobat software for developing all electronic copies of deliverables associated with the work assignment.

IV. Schedule of Deliverables

Task	Deliverable	Schedule
1	Work Plan	Per contract requirements
2	Revised QAPP	As necessary and/or as requested by the WACOR
2	Final QAPP	One month before work assignment completion
2	Information Quality Guidelines	Within 10 business days of completion of the work assignment
3	Revised DMP	As necessary and/or as requested by the WACOR
3	Final DMP	One month before work assignment completion
4	Biweekly updates on status state data collection efforts and data processing/standardization/conversion to XML format	As requested by the WACOR
5	Status update on state data migration	Within 5 business days of migration of state data
6	Status update on EPA data migration	As requested by the WACOR
7	Presentations, workgroup support	As requested by the WACOR

IV. Reporting:

The Contractor shall include all progress for this WA in the monthly report prepared for this contract. The monthly report shall also include any QA issues encountered and recommendations for resolution. Financial reports shall also be completed as specified in the contract. Financial reports shall also be completed as specified in the contract. The Contractor shall maintain a file of all documentation, including raw data, calculations, assumptions, telephone contacts, and sources of information.

During the period of performance of this work, the contractor shall immediately inform the EPA WACOR by email of any problems that may impede performance along with any corrective actions needed to solve the problem.

V. Contractor Identification:

Contractor personnel shall clearly identify corporate affiliation at the start of any meeting. While attending EPA-sponsored meetings, conferences, symposia, etc. or while on a Government site, Contractor personnel shall wear a badge which identifies the individual as a contractor employee. Contractor personnel are strictly prohibited from acting as a representative of the Agency at meetings, conferences, symposia, etc.

VI. Travel:

No travel is anticipated under this work assignment. However, any travel chargeable to this work assignment shall be allowable only in accordance with the limitation of FAR 31.205-43 and FAR 31.205-46, and must be approved by the EPA Project Officer prior to travel taking place.

VII. Printing:

All copying and printing shall be accomplished within the limitations of the printing clause of the contract.

VIII. Meetings, Conferences, Training Events, Award Ceremonies, and Receptions:

All appropriate clearances and approvals required by Agency policy in support of any and all conference related activities and expenses, including support of meetings, conferences, training events, award ceremonies and receptions, including the form 5170 for all meetings costing more than \$20,000, shall be obtained by the EPA CL COR as needed and provided to the Contracting Officer Work under conference-related activities and expenses shall not occur until this approval is obtained and provided by the EPA CL COR.

ATTACHMENT A

Office of Water Information Quality Guidelines Checklist for Non-Influential Information

Office of Water Information Quality Guidelines Checklist for Non-Influential Information

	The information to be disseminated is covered under The Guidelines.
	The information is in compliance with EPA's Quality System and other related policies
	The information is in compliance with Office of Water's Quality Management Plan.
	The information is consistent with the OMB definition of "quality," meaning the information has a high level of objectivity, utility, and integrity. Objectivity: information is presented in an accurate, clear, complete, and unbiased manner, and as a matter of substance, is accurate, reliable, and unbiased. Integrity: the information cannot be compromised through corruption or falsification because it is secure from unauthorized access or revision. Utility: the information is useful to the intended users.
	Meets "transparency" quality standard: the public can understand the source of the information and how conclusions were reached on the information.
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U.S. Environmental Protection Agency, Region 5, Great Lakes National Program Office

1.0 General

- **1.1** This work assignment supports environmental planning related to Lakes Superior and Huron.
- 1.2 Background: Lakewide Management under Annex 2 of the GLWQA is led by USEPA in the United States (and Environment and Climate Change Canada (ECCC) in Canada). EPA and ECCC collaborate with U.S. and Canadian environmental and natural resource management agencies, referred to collectively as "the Lake Partnership". The Lake Partnership has two levels: its Working Group and its Management Committee. There is a Lake Partnership for each of the five Lakes.

LAMPs assess environmental conditions on a whole-lake basis and identify restoration and protection priorities. LAMPs are developed for each Great Lake every five years, with the Erie LAMP scheduled for completion during 2018, Lake Michigan in 2019, Superior in 2020, Huron in 2021, and Ontario in 2022.

In addition, the Great Lakes Water Quality Agreement calls for a "Coordinated Science and Monitoring Initiative" (CSMI) for each of the lakes, on a five-year rotating basis. The next Lake Superior CSMI monitoring year is scheduled for 2021, with development of priorities in 2019 and finalization of actions in 2020. The Lake Huron CSMI reporting out is scheduled for 2019, with development of priorities scheduled for 2020, for the next monitoring year of 2022.

The LAMP for Huron was completed circa 2018. This document is well-developed and supplies a robust foundation for an update. It was developed with contract support from Battelle Memorial Institute. The Huron LAMP will be updated during 2021.

In general, the writing style of the CSMI monitoring priorities, matrix and background paper will be concise and use the active voice. The writing will be in plain English to serve federal, state and tribal resource staff and managers. The contractor shall provide document production support, spreadsheets, background papers, and technical editing. The contractor shall also draft an

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outline for the next Lake Huron LAMP as well as the 2020 Lake Superior chemical milestones report. EPA's COTR will coordinate within the working group and track contributions from government employees.

1.3 Scope of Work

- Lake Superior CSMI Priority Projects Matrix and background paper
- Workgroup and meeting support for Lake Superior and Lake Huron
- Lake Superior chemical milestones report
- Lake Huron LAMP draft outline
- Outreach and Engagement support

1.4 USEPA Points of Contact

Contracting Officer's Technical Representative (COTR) Elizabeth Laplante (312) 353-2694 Laplante.elizabeth@epa.gov

Alternate Contracting Officer Technical Representative (Alternate COTR) F. Anscombe (312) 353-0201

Anscombe.frank@epa.gov

Contracting Officer (CO)
Jessica White

2.0 Tasks

2.1: Work plan and work assignment management

2.2: Support to planning CSMI activities

Each of the Lakes has multiple jurisdictions that contribute to LAMP activities.

Every 5th year, one activity is called CSMI, Coordinated Science and Monitoring Initiative.

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CSMI generally entails coordination between the US and Canada, and their many affiliated jurisdictions, about what chemical, biological, or terrestrial metrics to sample and analyze, in order to better inform understanding of conditions in the environment.

The contractor shall work with government officials to compile their proposed monitoring parameters. Government stakeholders will share these with the public and invite suggestions and feedback about the monitoring game-plan.

The next CSMI year for Lake Superior will be 2021. To prepare for this, monitoring priorities must be developed, coordinated and finalized during 2020. The contractor shall coordinate conference calls, webinars and meetings of the CSMI workgroup. The contractor shall also summarize monitoring priorities with a 4 to 6 page spreadsheet, with an accompanying short explanatory report. The contractor shall receive inputs from USEPA and produce an integrated document, subject to acceptance by the COR. The contractor shall contribute grammar, readability, and technical editing. Examples of reports may be found attached.

In addition, the contractor shall develop a list of Lake Huron CSMI priorities. These priorities will be listed in a spreadsheet, with accompanying explanation.

2.3: Outreach and Engagement activities

Contractor shall work with the Lake Superior and Lake Huron workgroups, especially the O and E committees, to develop O and E strategies about LAMPs, CSMI, State of the Lake and other GLWQA activities.

The contractor shall support one Superior and one Huron public outreach webinar and one "in-person" meeting, during this performance period.

Contractor will convene conference calls and help develop O and E strategies which will support management processes for these two lakes. After the COR provides an agenda, the contractor shall draft information to share with outside stakeholders.

2.4 Support to lake workgroups

The contractor shall support lake-wide planning by workgroups addressing Lakes Superior and Huron. In general, there are two meetings per calendar year for each lake. Superior meetings are usually three days in duration, plus travel time on either end. Huron is usually two days.

The contractor shall attend one Lake Huron and one Lake Superior meeting during the contractor period. The contractor shall also attend conference calls leading up to these in person sessions. Support will include drafting action items, notes and minutes of meetings.

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2.5 Chemical milestones report outline

The contractor shall put together a draft preliminary outline for the chemical milestones report 2020, similar to the most recent milestones report written in 2015.

2.6 Huron LAMP Outline

During early 2020, the Contractor shall draft an outline for the Lake Huron LAMP, based on inputs and comments from the Huron partnership.

3.0 Applicable Documents

Lake Huron LAMP (https://binational.net/2018/04/09/lhlamp-pddplh2/) is the model for technical writing and LAMP development.

- **4.0 Places of Performance**: During 2019-2020, one "in person" meeting each will take place in Superior watershed and one in the watershed of Lake Huron.
- **5.0 Milestones Table**: The contractor shall provide all documents in original source formatting, in addition to MS Word and PDF.

Task	Milestones	Format	Deliverables due
2.1	Workplan and management	Word document and	Proposed workplan due
		*.PDF document emailed	within two weeks of start
		to COR. Upload in	of work assignment
		FedConnect.	
2.2	CSMI monitoring priorities for Lakes	Word document and	Superior1st draft
	Superior and Huron	*.PDF document emailed	December 2019
		to COR. Upload in	
		FedConnect.	2 nd draft Superior May
			2020
			1st draft Huron May 2020
2.3	Outreach and Engagement	Word document and	O&E information for
		*.PDF document emailed	Superior, one meeting and
			one webinar, by May 2020

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		to COR. Upload in	
		FedConnect.	Information for Huron, one
			meeting and one webinar,
			May 2020
2.4	Meetings of the two governmental	Word document and	Attend two meetings and
	workgroups	*.PDF document emailed	provide minutes to
		to COR. Upload in	memorialize decisions and
		FedConnect.	action items
2.5	Outline chemical milestones report	Word document and	May 2020
		*.PDF document emailed	
		to COR. Upload in	
		FedConnect.	
2.6	Huron LAMP outline	Word document and	1st draft 20 days after EPA
		*.PDF document emailed	inputs (circa April 2020).
		to COR. Upload in	
		FedConnect.	

6.0 Period of Performance: from award thru end of the performance period of the master contract (estimated to be June 2020).